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REMARKS

Claim Status

Claims 1-32 are pending in this application. Claims 2-10, 25, 26 and 28-32 have been withdrawn from consideration pursuant to a restriction and election of species requirement. Claims 1, 11-24 and 27 are currently under consideration.

Claim Rejection under 35 USC 103(a)—Henderson, Antwerp, Forster, Pinchuk

Claims 1, 13-16 and 19-24 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson, Antwerp or Forster, each taken alone or in view of Pinchuk US 5,741,331. These rejections are respectfully traversed.

None of the three primary references of record discloses an enzyme (on an article) disposed within a polymer matrix, as required by the instant claims.

In particular, the Office Action indicates that Hendrickson discloses enzymes immobilized on the surface of a treated fibrous support (*see* Hendrickson, col. 3, line 53 to col. 4, line 29). However, the Examiner fails to appreciate that coating such an immobilized enzyme with a polymer, would result in an enzyme being disposed under a matrix, rather than within a matrix as claimed.

Similarly, Antwerp discloses an enzyme bound to the article itself that is then coated with a starch based encapsulating coating (*see* Antwerp, col. 5, lines 4-8).

Forster merely discloses an enzyme coated (immobilized) directly on a vascular prosthesis itself and nothing relevant further.

It is respectfully submitted that the rejection based only on these references is improper on its face. The Examiner has presented no reasoning to support a conclusion of obviousness for a medical device (stent or any prosthetic article) coated with the recited polymer matrix within which an enzyme of any type is disposed, much less enzymes of the type claimed in the instant invention. *See* MPEP § 706.02(j)(D) and the cases cited therein. Applicant has discovered that when the enzyme is disposed within a polymer matrix at or near a surface of said medical article, it is important that the enzyme be held “in place, while at the same time allowing diffusion of substrates into and diffusion of products out of the matrix.” (specification, paragraph [0030]). None of the cited references teach or suggest the structural significance of Applicant’s claimed

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polymeric matrix article. This is not surprising since the cited references do not seek to achieve the purpose articulated in claim 1: that is, creating enzyme activity in the matrix while at the same time, allowing diffusion of substrates into and diffusion of products out of the matrix. The Examiner has provided no evidence to show otherwise.

The Examiner further turns to Pinchuk for its purported teaching of relevant polymers for various types of implantable articles. See column 1, lines 33-40. However, such a teaching fails to remedy the deficiencies in Henderson, Antwerp and Forster that are cited above. There appears to be no teaching in Pinchuk of an enzymatically active polymeric matrix, nor does there appear to be any teaching regarding diffusion of enzymatic substrates into, and diffusion of enzymatic products out of, a matrix. Thus, the Henderson, Antwerp and Foster references, either singly or in combination with Pinchuk, fail to establish a *prima facie* case of obviousness. Accordingly, reconsideration and withdrawal of the rejections of claims 1, 13-16 and 19-24 as being unpatentable over Hendrickson, Antwerp or Forster, each taken alone or in view of Pinchuk, are therefore requested.

Claim Rejection under 35 USC 103(a)—Sivan and Pinchuk

Claims 1, 11-16, 19-24 and 27 have been rejected under 35 U.S.C. 103(e) as being unpatentable over Sivan in view of Pinchuk. This rejection is respectfully traversed for several reasons.

Sivan discloses a medical device bearing a relevant enzyme. However, the enzyme is either bonded directly to the surface of the article or is entrapped within a "hydrogel" (see Sivan, col. 5, lines 3-4). The only hydrogel disclosed is an interpolymer of an acryloxysilane, diacrylyl polyethylene glycol and the enzyme itself (col. 5, lines 4-9), that together form a polymeric hydrogel network. Thus, in Sivan, the enzyme is the matrix, rather than disposed within a matrix, as claimed.

Secondly, the other polymers disclosed at column 3 of Sivan and referred to by the Examiner constitute the materials from which the body of the stent itself is made. They are not used as a matrix that is disposed on a medical article, much less one which carries an enzyme. Indeed, Sivan states that

Biologically active agents 8 are preferably immobilized to outer surface 4 and inner surface 6 of stent 2....Stent 2 is preferably made of metal such as

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platinum, gold, titanium, and nickel. Alternatively, stent 2 may be made of metal alloys such as stainless steel and nickel-titanium alloy (nitinol). Alternatively stent 2 may be made of non-degradable polymers or copolymers such as polyethylene, polypropylene, poly(acrylic acid), poly(ethylene oxide), and poly(ethylene oxide-co-propylene oxide). Preferably, stent 2 is coated with a layer of a crosslinked polymer, or alternatively protein, so as to confer biocompatibility characteristics to the stent.

(col. 3, line 54 to col. 4, line 3)(emphasis added).

There is no further discussion of the "crosslinked polymer" or "protein" quoted above, which coat the stent.

Regarding Pinchuk, although Pinchuk discloses relevant polymers, the combination of that disclosure with the disclosure of Sivan would at best result in a stent itself made of those polymers, *see supra*, and not the subject matter of the instant claims.

To combine the references to result in the here claimed invention would rely on undue hindsight as discussed above. Reconsideration and withdrawal of the rejections of claims 1, 11-16, 19-24 and 27 as being unpatentable over Sivan in view of Pinchuk are therefore requested.

Rejections of claims 17 and 18 under 35 U.S.C 103(a)

Claims 17 and 18 have been rejected under 35 U.S.C 103(a) as being unpatentable over the foregoing combinations of references taken together with Applicant's acknowledgements of prior art. These rejections are respectfully traversed.

The limitations added by claims 17 and 18 rely on techniques that were generally known. However, these rejections fail at their crux for the reasons discussed above with respect to the other rejections.

Reconsideration and withdrawal of the rejections of claims 17 and 18 are requested.

CONCLUSION

In light of the foregoing remarks, applicants believe that all rejections of record have been obviated, and allowance of this application is respectfully requested. If the

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Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

FEES

While it is not believed that any fees are due as a result of this Response, the Examiner is authorized to charge any fees that may be due to the undersigned attorney's PTO Deposit Account #50-1047.

Respectfully submitted,

By:



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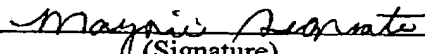
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this document, and any document referenced herein, has been transmitted via facsimile to the US Patent and Trademark Office at (703) 872-9306 on 6/15/05.

Marjorie Scariati

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